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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,502	12/17/2001	Kelly Moran	BJA219A	4304

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

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DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/023,502

Applicant(s)

MORAN, KELLY

Examiner

Kennedy Schaetzle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Specification*

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: There is no antecedent basis for claim 13's reference to a spiral pattern of radiation application.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear in claim 11 what steps of the method are being alluded to or set forth by stating that the method enhances healing as effectively for diabetes patients as for normal patients. Claim 11 merely appears to be a recitation of a desired outcome and – if not already inherent in the method of claim 1-- does not contain the necessary steps to bring about such an outcome.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolff (Pat. No. 4,287,554).

Wolff discloses that the electromagnetic radiation produced by his device may be employed to treat acne, psoriasis, or other skin related disorders. It should be noted that applicant's claim 1 is drafted so broadly that it reads on someone with acne or an insect bite stepping outside into the sunlight, or simply turning on a reading lamp.

Regarding claim 11, note the comments above in the rejection of the claim under 35 USC §112, 2<sup>nd</sup> paragraph.

Regarding claim 12, the examiner considers the radiation produced by the Wolff device to be inherently capable of eradicating bacteria and viral bodies.

6. Claims 1-4, 6-8, 11 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Whitehurst (Pat. No. 6,461,866).

Whitehurst discloses the use of a non-coherent, non-ablative light source useful in the cosmetic treatment of dermatological conditions such as portwine stains, psoriasis, etc. (col. 3, lines 32-46) with an output intensity of generally greater than 1 W/cm<sup>2</sup> (col. 1, lines 65-67), which can be focused and delivered via at least one optical fiber (col. 2, lines 4-7) at wavelengths in the range of 193 nm to 3 micrometers (col. 3, lines 47-53) and treatment times of 0-9999 seconds (col. 4, lines 29-36).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff (Pat. No. 4,287,554).

Regarding claim 2, the examiner considers the power density of the Wolff device to be at least  $1 \text{ W/cm}^2$  given the effects produced by the application of radiation energy. Since Wolff discloses that skin disorders such as acne and psoriasis may be effectively treated, the power density must be of a sufficient magnitude in order for any beneficial results to occur. Such a magnitude would necessarily be of a similar strength to the applicant's device since it also treats the same conditions by electromagnetic radiation of a similar wavelength. Concerning the exposure times, Wolff discloses that treatment times may correspond to the performance of mundane acts such as brushing ones teeth or combing one's hair. The examiner considers such acts to reasonably fall within the 1 second to 3 minute exposure time.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst.

While Whitehurst employs non-coherent light in the practice of his invention instead of coherent light (i.e., laser) due to the disadvantages listed in col. 1, lines 12-32 (e.g., high cost, size, power consumption, sophistication, etc.), it is well known in the art that coherent light may be used effectively despite its cost, size and complexity. Whether a system is more costly to purchase, takes up more space, or requires a higher skill level to operate does not negate the fact that such a system can be effective to treat skin disorders such as discussed by Whitehurst. By analogy, a diamond tipped jackhammer may be more costly to purchase and thus not recommended for use, yet such a tool would hardly be considered novel or unobvious given the known properties of diamonds. Likewise, given the known effectiveness of coherent light in treating dermatological disorders, those of ordinary skill in the art would have considered the use of a coherent light source such as a laser to be obvious for the healing of stage one and stage two wounds.

10. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst in view of Talmore (Pat. No. 5,344,433).

Whitehurst does not appear to explicitly discuss the average power of the radiation energy produced by the 300 W Xenon short arc lamp. Talmore, however, discloses the use of an identical light source and states that the lamp provides a light

beam with an output of 1W (col. 4, lines 5-13). It would appear that the particular level of radiation power desired would depend upon the application at hand and the particular skin condition being treated. Lacking any criticality by the applicant in regards to providing a 1W output or a 5 to 10 W output, those of ordinary skill in the art would have seen the particular power level to be an obvious matter of design dependent upon the conditions of the particular wound being treated.

11. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehurst in view of Neuberger (Pat. No. 6,165,205).

Whitehurst does not explicitly discuss the step of applying radiation in a spiral pattern. Neuberger discloses that it is known to use spiral patterns when treating tissues with radiation (col. 4, lines 12-23). The applicant gives no criticality in employing spiral patterns over any other pattern. As Whitehurst enables application of focused energy via optical fiber means, thus permitting one to direct the energy in a controlled manner to specific portions of the body, and as the use of spiral patterns when applying treatment energy are known by those of ordinary skill in the art, it would have been obvious to employ any application technique ensuring proper coverage of the treatment area.

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

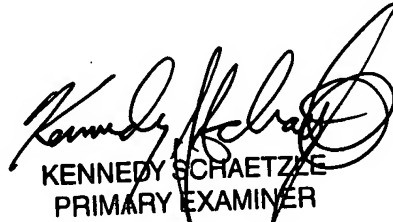
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS  
May 3, 2004



KENNEDY SCHAEETZLE  
PRIMARY EXAMINER